

114TH CONGRESS  
1ST SESSION

# H. R. 2629

To amend the Federal Food, Drug, and Cosmetic Act with respect to the approval of certain antibacterial and antifungal drugs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 3, 2015

Mr. SHIMKUS (for himself and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the approval of certain antibacterial and antifungal drugs, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Antibiotic Development  
5       to Advance Patient Treatment Act”.

6       **SEC. 2. APPROVAL OF CERTAIN DRUGS FOR USE IN A LIM-**  
7                   **ITED POPULATION OF PATIENTS.**

8       (a) PURPOSE.—The purpose of this section is to help  
9       expedite the development and availability of treatments for  
10      serious or life-threatening bacterial or fungal infections in

1 patients with unmet needs, while maintaining safety and  
2 effectiveness standards for such treatments, taking into  
3 account the severity of the infection and the availability  
4 or lack of alternative treatments.

5 (b) APPROVAL OF CERTAIN ANTIBACTERIAL AND  
6 ANTIFUNGAL DRUGS.—Section 505 of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 355) is amended by  
8 adding at the end the following new subsection:

9 “(x) APPROVAL OF CERTAIN ANTIBACTERIAL AND  
10 ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPU-  
11 LATION OF PATIENTS.—

12 “(1) PROCESS.—At the request of the sponsor  
13 of an antibacterial or antifungal drug that is in-  
14 tended to treat a serious or life-threatening infec-  
15 tion, the Secretary—

16 “(A) may execute a written agreement  
17 with the sponsor on the process for developing  
18 data to support an application for approval of  
19 such drug, for use in a limited population of pa-  
20 tients in accordance with this subsection;

21 “(B) shall proceed in accordance with this  
22 subsection only if a written agreement is  
23 reached under subparagraph (A);

1               “(C) shall provide the sponsor with an op-  
2 portunity to request meetings under paragraph  
3 (2);

4               “(D) if a written agreement is reached  
5 under subparagraph (A), may approve the drug  
6 under this subsection for such use—

7               “(i) in a limited population of patients  
8 for which there is an unmet medical need;

9               “(ii) based on a streamlined develop-  
10 ment program; and

11               “(iii) only if the standards for ap-  
12 proval under subsections (c) and (d) of this  
13 section or licensure under section 351 of  
14 the Public Health Service Act, as applica-  
15 ble, are met; and

16               “(E) in approving a drug in accordance  
17 with this subsection, subject to subparagraph  
18 (D)(iii), may rely upon—

19               “(i) traditional endpoints, alternate  
20 endpoints, or a combination of traditional  
21 and alternate endpoints, and, as appro-  
22 priate, data sets of a limited size; and

23               “(ii)(I) additional data, including pre-  
24 clinical, pharmacologic, or pathophysiologic  
25 evidence;

1                         “(II) nonclinical susceptibility and  
2                         pharmacokinetic data;

3                         “(III) data from phase 2 clinical  
4                         trials; and

5                         “(IV) such other confirmatory evi-  
6                         dence as the Secretary determines appro-  
7                         priate to approve the drug.

8                         “(2) FORMAL MEETINGS.—

9                         “(A) IN GENERAL.—To help expedite and  
10                         facilitate the development and review of a drug  
11                         for which a sponsor intends to request approval  
12                         in accordance with this subsection, the Sec-  
13                         retary may, at the request of the sponsor, con-  
14                         duct meetings that provide early consultation,  
15                         timely advice, and sufficient opportunities to  
16                         develop an agreement described in paragraph  
17                         (1)(A) and help the sponsor design and conduct  
18                         a drug development program as efficiently as  
19                         possible, including the following types of meet-  
20                         ings:

21                         “(i) An early consultation meeting.

22                         “(ii) An assessment meeting.

23                         “(iii) A postapproval meeting.

24                         “(B) NO ALTERING OF GOALS.—Nothing  
25                         in this paragraph shall be construed to alter

1       agreed upon goals and procedures identified in  
2       the letters described in section 101(b) of the  
3       Prescription Drug User Fee Amendments of  
4       2012.

5           “(C) BREAKTHROUGH THERAPIES.—In the  
6       case of a drug designated as a breakthrough  
7       therapy under section 506(a), the sponsor of  
8       such drug may elect to utilize meetings pro-  
9       vided under such section with respect to such  
10      drug in lieu of meetings described in subpara-  
11      graph (A).

12          “(3) LABELING REQUIREMENT.—The labeling  
13      of an antibacterial or antifungal drug approved in  
14      accordance with this subsection shall contain the  
15      statement ‘Limited Population’ in a prominent man-  
16      ner and adjacent to, and not more prominent than,  
17      the brand name of the product. The prescribing in-  
18      formation for such antibacterial or antifungal drug  
19      required by section 201.57 of title 21, Code of Fed-  
20      eral Regulations (or any successor regulation) shall  
21      also include the following statement: ‘This drug is  
22      indicated for use in a limited and specific population  
23      of patients.’.

24          “(4) PROMOTIONAL MATERIALS.—The provi-  
25      sions of section 506(c)(2)(B) shall apply with re-

1       spect to approval in accordance with this subsection  
2       to the same extent and in the same manner as such  
3       provisions apply with respect to accelerated approval  
4       in accordance with section 506(c)(1).

5           “(5) TERMINATION OF REQUIREMENTS OR CON-  
6       DITIONS.—If a drug is approved in accordance with  
7       this subsection for an indication in a limited popu-  
8       lation of patients and is subsequently approved or li-  
9       censed under this section or section 351 of the Pub-  
10      lic Health Service Act, other than in accordance with  
11      this subsection, for—

12           “(A) the same indication and the same  
13       conditions of use, the Secretary shall remove  
14       any labeling requirements or postmarketing  
15       conditions that were made applicable to the  
16       drug under this subsection; or

17           “(B) a different indication or condition of  
18       use, the Secretary shall not apply the labeling  
19       requirements and postmarketing conditions that  
20       were made applicable to the drug under this  
21       subsection to the subsequent approval of the  
22       drug for such different indication or condition  
23       of use.

24           “(6) RELATION TO OTHER PROVISIONS.—Noth-  
25       ing in this subsection shall be construed to prohibit

1       the approval of a drug for use in a limited popu-  
2       lation of patients in accordance with this subsection,  
3       in combination with—

4               “(A) an agreement on the design and size  
5               of a clinical trial pursuant to subparagraphs  
6               (B) and (C) of subsection (b)(5);

7               “(B) designation and treatment of the  
8               drug as a breakthrough therapy under section  
9               506(a);

10               “(C) designation and treatment of the  
11               drug as a fast track product under section  
12               506(b); or

13               “(D) accelerated approval of the drug in  
14               accordance with section 506(c).

15       “(7) RULE OF CONSTRUCTION.—Nothing in  
16       this subsection shall be construed—

17               “(A) to alter the standards of evidence  
18               under subsection (c) or (d) (including the sub-  
19               stantial evidence standard in subsection (d));

20               “(B) to waive or otherwise preclude the ap-  
21               plication of requirements under subsection (o);

22               “(C) to otherwise, in any way, limit the au-  
23               thority of the Secretary to approve products  
24               pursuant to this Act and the Public Health

1           Service Act as authorized prior to the date of  
2           enactment of this subsection; or

3           “(D) to restrict in any manner, the pre-  
4           scribing of antibiotics or other products by  
5           health care providers, or to otherwise limit or  
6           restrict the practice of health care.

7           “(8) EFFECTIVE IMMEDIATELY.—The Sec-  
8           retary shall have the authorities vested in the Sec-  
9           retary by this subsection beginning on the date of  
10          enactment of this subsection, irrespective of when  
11          and whether the Secretary promulgates final regula-  
12          tions or guidance.

13          “(9) DEFINITIONS.—In this subsection:

14           “(A) EARLY CONSULTATION MEETING.—  
15          The term ‘early consultation meeting’ means a  
16          pre-investigational new drug meeting or an end-  
17          of-phase 1 meeting that—

18           “(i) is conducted to review and reach  
19          a written agreement—

20           “(I) on the scope of the stream-  
21          lined development plan for a drug for  
22          which a sponsor intends to request ap-  
23          proval in accordance with this sub-  
24          section; and

1                         “(II) which, as appropriate, may  
2                         include agreement on the design and  
3                         size of necessary preclinical and clin-  
4                         ical studies early in the development  
5                         process, including clinical trials whose  
6                         data are intended to form the primary  
7                         basis for an effectiveness claim; and

8                         “(ii) provides an opportunity to dis-  
9                         cuss expectations of the Secretary regard-  
10                         ing studies or other information that the  
11                         Secretary deems appropriate for purposes  
12                         of applying paragraph (5), relating to the  
13                         termination of labeling requirements or  
14                         postmarketing conditions.

15                         “(B) ASSESSMENT MEETING.—The term  
16                         ‘assessment meeting’ means an end-of-phase 2  
17                         meeting, pre-new drug application meeting, or  
18                         pre-biologics license application meeting con-  
19                         ducted to resolve questions and issues raised  
20                         during the course of clinical investigations, and  
21                         details addressed in the written agreement re-  
22                         garding postapproval commitments or expan-  
23                         sion of approved uses.

24                         “(C) POSTAPPROVAL MEETING.—The term  
25                         ‘postapproval meeting’ means a meeting fol-

1           lowing initial approval or licensure of the drug  
2           for use in a limited population, to discuss any  
3           issues identified by the Secretary or the sponsor  
4           regarding postapproval commitments or expan-  
5           sion of approved uses.”.

6         (c) GUIDANCE.—Not later than 18 months after the  
7    date of enactment of this Act, the Secretary of Health and  
8    Human Services, acting through the Commissioner of  
9    Food and Drugs, shall issue draft guidance describing cri-  
10   teria, process, and other general considerations for dem-  
11   onstrating the safety and effectiveness of antibacterial and  
12   antifungal drugs to be approved for use in a limited popu-  
13   lation in accordance with section 505(x) of the Federal  
14   Food, Drug, and Cosmetic Act, as added by subsection  
15   (b).

16         (d) CONFORMING AMENDMENTS.—

17           (1) LICENSURE OF CERTAIN BIOLOGICAL PROD-  
18   UCTS.—Section 351(j) of the Public Health Service  
19   Act (42 U.S.C. 262(j)) is amended—

20                  (A) by striking “(j)” and inserting  
21                  “(j)(1)”;

22                  (B) by inserting “505(x),” after “505(p),”;  
23                  and

24                  (C) by adding at the end the following new  
25                  paragraph:

1       “(2) In applying section 505(x) of the Federal Food,  
2 Drug, and Cosmetic Act to the licensure of biological prod-  
3 ucts under this section—

4           “(A) references to an antibacterial or antifungal  
5 drug that is intended to treat a serious or life-  
6 threatening infection shall be construed to refer to  
7 a biological product intended to treat a serious or  
8 life-threatening bacterial or fungal infection; and

9           “(B) references to approval of a drug under  
10 section 505(c) of such Act shall be construed to  
11 refer to a licensure of a biological product under  
12 subsection (a) of this section.”.

13           (2) MISBRANDING.—Section 502 of the Federal  
14 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is  
15 amended by adding at the end the following new  
16 subsection:

17           “(dd) If it is a drug approved in accordance with sec-  
18 tion 505(x) and its labeling does not meet the require-  
19 ments under paragraph (3) of such subsection, subject to  
20 paragraph (5) of such subsection.”.

21           (e) EVALUATION.—

22           (1) ASSESSMENT.—Not later than 48 months  
23 after the date of enactment of this Act, the Sec-  
24 retary of Health and Human Services shall publish  
25 for public comment an assessment of the program

1       established under section 505(x) of the Federal  
2       Food, Drug, and Cosmetic Act, as added by sub-  
3       section (b). Such assessment shall determine if the  
4       limited-use pathway established under such section  
5       505(x) has improved or is likely to improve patient  
6       access to novel antibacterial or antifungal treat-  
7       ments and assess how the pathway could be ex-  
8       panded to cover products for serious or life-threat-  
9       ening diseases or conditions beyond bacterial and  
10      fungal infections.

11                   (2) MEETING.—Not later than 90 days after  
12       the date of the publication of such assessment, the  
13       Secretary, acting through the Commissioner of Food  
14       and Drugs shall hold a public meeting to discuss the  
15       findings of the assessment, during which public  
16       stakeholders may present their views on the success  
17       of the program established under section 505(x) of  
18       the Federal Food, Drug, and Cosmetic Act, as  
19       added by subsection (b), and the appropriateness of  
20       expanding such program.

21                   (f) EXPANSION OF PROGRAM.—If the Secretary of  
22       Health and Human Services determines, based on the as-  
23       essment under subsection (e)(1), evaluation of the assess-  
24       ment, and any other relevant information, that the public  
25       health would benefit from expansion of the limited-use

1 pathway established under section 505(x) of the Federal  
2 Food, Drug, and Cosmetic Act (as added by subsection  
3 (b)) beyond the drugs approved in accordance with such  
4 section, the Secretary may expand such limited-use path-  
5 way in accordance with such a determination. The ap-  
6 proval of any drugs under any such expansion shall be  
7 subject to the considerations and requirements described  
8 in such section 505(x) for purposes of expansion to other  
9 serious or life-threatening diseases or conditions.

10 (g) MONITORING.—The Public Health Service Act is  
11 amended by inserting after section 317T (42 U.S.C.  
12 247b–22) the following:

13 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**  
14 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

15 “(a) MONITORING.—The Secretary shall use an ap-  
16 propriate monitoring system to monitor—

17 “(1) the use of antibacterial and antifungal  
18 drugs, including those receiving approval or licensure  
19 for a limited population pursuant to section 505(x)  
20 of the Federal Food, Drug, and Cosmetic Act; and  
21 “(2) changes in bacterial and fungal resistance  
22 to drugs.

23 “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-  
24 retary shall make summaries of the data derived from

1 monitoring under this section publicly available for the  
2 purposes of—

3           “(1) improving the monitoring of important  
4 trends in antibacterial and antifungal resistance;  
5 and

6           “(2) ensuring appropriate stewardship of anti-  
7 bacterial and antifungal drugs, including those re-  
8 ceiving approval or licensure for a limited population  
9 pursuant to section 505(x) of the Federal Food,  
10 Drug, and Cosmetic Act.”.

11 **SEC. 3. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**

12           **FOR MICROORGANISMS.**

13       (a) IN GENERAL.—Section 511 of the Federal Food,  
14 Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to  
15 read as follows:

16 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**  
17           **TEST INTERPRETIVE CRITERIA FOR MICRO-**  
18           **ORGANISMS.**

19       “(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

20           “(1) PURPOSE.—The purpose of this section is  
21 to provide the Secretary with an expedited, flexible  
22 method for—

23           “(A) clearance or premarket approval of  
24 antimicrobial susceptibility testing devices uti-  
25 lizing updated, recognized susceptibility test in-

1           terpretive criteria to characterize the in vitro  
2           susceptibility of particular bacteria, fungi, or  
3           other microorganisms to antimicrobial drugs;  
4           and

5           “(B) providing public notice of the avail-  
6           ability of recognized interpretive criteria to  
7           meet premarket submission requirements or  
8           other requirements under this Act for anti-  
9           microbial susceptibility testing devices.

10          “(2) IN GENERAL.—The Secretary shall iden-  
11          tify appropriate susceptibility test interpretive cri-  
12          teria with respect to antimicrobial drugs—

13           “(A) if such criteria are available on the  
14           date of approval of the drug under section 505  
15           of this Act or licensure of the drug under sec-  
16           tion 351 of the Public Health Service Act (as  
17           applicable), upon such approval or licensure; or

18           “(B) if such criteria are unavailable on  
19           such date, on the date on which such criteria  
20           are available for such drug.

21          “(3) BASES FOR INITIAL IDENTIFICATION.—  
22          The Secretary shall identify appropriate suscepti-  
23          bility test interpretive criteria under paragraph (2),  
24          based on the Secretary’s review of, to the extent  
25          available and relevant—

1               “(A) preclinical and clinical data, including  
2               pharmacokinetic, pharmacodynamic, and epidemiological data;

4               “(B) Bayesian and pharmacometric statistical methodologies; and

6               “(C) such other evidence and information  
7               as the Secretary considers appropriate.

8       **“(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**

9   **WEBSITE.—**

10              “(1) IN GENERAL.—Not later than 1 year after  
11              the date of the enactment of the Antibiotic Development to Advance Patient Treatment Act, the Secretary shall establish, and maintain thereafter, on  
12              the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards in accordance with paragraph (2)  
13              (referred to in this section as the ‘Interpretive Criteria Website’).

20              “(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS.—

22              “(A) IN GENERAL.—The list described in  
23              paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

1                     “(i) established by a nationally or  
2                     internationally recognized standard devel-  
3                     opment organization that—

4                         “(I) establishes and maintains  
5                     procedures to address potential con-  
6                     flicts of interest and ensure trans-  
7                     parent decisionmaking;

8                         “(II) holds open meetings to en-  
9                     sure that there is an opportunity for  
10                     public input by interested parties, and  
11                     establishes and maintains processes to  
12                     ensure that such input is considered  
13                     in decisionmaking; and

14                         “(III) permits its standards to be  
15                     made publicly available, through the  
16                     National Library of Medicine or an-  
17                     other similar source acceptable to the  
18                     Secretary; and

19                         “(ii) recognized in whole, or in part,  
20                     by the Secretary under subsection (c).

21                         “(B) OTHER LIST.—The Interpretive Cri-  
22                     teria Website shall, in addition to the list de-  
23                     scribed in subparagraph (A), include a list of  
24                     interpretive criteria, if any, that the Secretary  
25                     has determined to be appropriate with respect

1           to legally marketed antimicrobial drugs,  
2        where—

3               “(i) the Secretary does not recognize,  
4               in whole or in part, an interpretive criteria  
5               standard described under subparagraph  
6               (A) otherwise applicable to such a drug;

7               “(ii) the Secretary withdraws under  
8               subsection (c)(1)(B) recognition of a  
9               standard, in whole or in part, otherwise  
10              applicable to such a drug;

11               “(iii) the Secretary approves an applica-  
12               tion under section 505 of this Act or sec-  
13               tion 351 of the Public Health Service Act,  
14               as applicable, with respect to marketing of  
15               such a drug for which there are no rel-  
16               evant interpretive criteria included in a  
17               standard recognized by the Secretary  
18               under subsection (c); or

19               “(iv) because the characteristics of  
20               such a drug differ from other drugs with  
21               the same active ingredient, the interpretive  
22               criteria with respect to such drug—

23               “(I) differ from otherwise appli-  
24               cable interpretive criteria included in  
25               a standard listed under subparagraph

1                             (A) or interpretive criteria otherwise  
2                             listed under this subparagraph; and

3                             “(II) are determined by the Sec-  
4                             retary to be appropriate for the drug.

5                             “(C) REQUIRED STATEMENTS OF LIMITA-  
6                             TIONS OF INFORMATION.—The Interpretive Cri-  
7                             teria Website shall include the following:

8                             “(i) A statement that—

9                                 “(I) the website provides infor-  
10                             mation about the susceptibility of bac-  
11                             teria, fungi, or other microorganisms  
12                             to a certain drug (or drugs); and

13                                 “(II) the safety and efficacy of  
14                             the drug in treating clinical infections  
15                             due to such bacteria, fungi, or other  
16                             microorganisms may not have been es-  
17                             tablished in adequate and well-con-  
18                             trolled clinical trials and the clinical  
19                             significance of such susceptibility in-  
20                             formation in such trials is unknown.

21                             “(ii) A statement that directs health  
22                             care practitioners to consult the approved  
23                             product labeling for specific drugs to deter-  
24                             mine the uses for which the Food and

1                   Drug Administration has approved the  
2                   product.

3                   “(iii) Any other statement that the  
4                   Secretary determines appropriate to ade-  
5                   quately convey the limitations of the data  
6                   supporting susceptibility test interpretive  
7                   criteria standard listed on the website.

8                   “(3) NOTICE.—Not later than the date on  
9                   which the Interpretive Criteria Website is estab-  
10                  lished, the Secretary shall publish a notice of that  
11                  establishment in the Federal Register.

12                  “(4) INAPPLICABILITY OF MISBRANDING PROVI-  
13                  SION.—The inclusion in the approved labeling of an  
14                  antimicrobial drug of a reference or hyperlink to the  
15                  Interpretive Criteria Website, in and of itself, shall  
16                  not cause the drug to be misbranded in violation of  
17                  section 502, or the regulations promulgated there-  
18                  under.

19                  “(5) TRADE SECRETS AND CONFIDENTIAL IN-  
20                  FORMATION.—Nothing in this section shall be con-  
21                  strued as authorizing the Secretary to disclose any  
22                  information that is a trade secret or confidential in-  
23                  formation subject to section 552(b)(4) of title 5,  
24                  United States Code.

1       “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-  
2 PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-  
3 GANIZATIONS.—

4           “(1) IN GENERAL.—Beginning on the date of  
5       the establishment of the Interpretive Criteria  
6       Website, and at least every 6 months thereafter, the  
7       Secretary shall—

8           “(A) evaluate any appropriate new or up-  
9       dated susceptibility test interpretive criteria  
10      standards established by a nationally or inter-  
11      nationally recognized standard development or-  
12      ganization described in subsection (b)(2)(A)(i);  
13      and

14           “(B) publish on the public website of the  
15       Food and Drug Administration a notice—

16           “(i) withdrawing recognition of any  
17       different susceptibility test interpretive cri-  
18       teria standard, in whole or in part;

19           “(ii) recognizing the new or updated  
20       standards;

21           “(iii) recognizing one or more parts of  
22       the new or updated interpretive criteria  
23       specified in such a standard and declining  
24       to recognize the remainder of such stand-  
25       ard; and

1                         “(iv) making any necessary updates to  
2                         the lists under subsection (b)(2).

3                         “(2) BASES FOR UPDATING INTERPRETIVE CRI-  
4                         TERIA STANDARDS.—In evaluating new or updated  
5                         susceptibility test interpretive criteria standards  
6                         under paragraph (1)(A), the Secretary may con-  
7                         sider—

8                         “(A) the Secretary’s determination that  
9                         such a standard is not applicable to a particular  
10                         drug because the characteristics of the drug dif-  
11                         fer from other drugs with the same active in-  
12                         gredient;

13                         “(B) information provided by interested  
14                         third parties, including public comment on the  
15                         annual compilation of notices published under  
16                         paragraph (3);

17                         “(C) any bases used to identify suscepti-  
18                         bility test interpretive criteria under subsection  
19                         (a)(2); and

20                         “(D) such other information or factors as  
21                         the Secretary determines appropriate.

22                         “(3) ANNUAL COMPILED OF NOTICES.—  
23                         Each year, the Secretary shall compile the notices  
24                         published under paragraph (1)(B) and publish such  
25                         compilation in the Federal Register and provide for

1       public comment. If the Secretary receives comments,  
2       the Secretary will review such comments and, if the  
3       Secretary determines appropriate, update pursuant  
4       to this subsection susceptibility test interpretive cri-  
5       teria standards—

6                 “(A) recognized by the Secretary under  
7       this subsection; or

8                 “(B) otherwise listed on the Interpretive  
9       Criteria Website under subsection (b)(2).

10                “(4) RELATION TO SECTION 514(c).—Any sus-  
11       ceptibility test interpretive standard recognized  
12       under this subsection or any criteria otherwise listed  
13       under subsection (b)(2)(B) shall be deemed to be  
14       recognized as a standard by the Secretary under sec-  
15       tion 514(c)(1).

16                “(5) VOLUNTARY USE OF INTERPRETIVE CRI-  
17       TERIA.—Nothing in this section prohibits a person  
18       from seeking approval or clearance of a drug or de-  
19       vice, or changes to the drug or the device, on the  
20       basis of susceptibility test interpretive criteria stand-  
21       ards which differ from those recognized pursuant to  
22       paragraph (1).

23                “(d) ANTIMICROBIAL DRUG LABELING.—

24                “(1) DRUGS MARKETED PRIOR TO ESTABLISH-  
25       MENT OF INTERPRETIVE CRITERIA WEBSITE.—With

1 respect to an antimicrobial drug lawfully introduced  
2 or delivered for introduction into interstate com-  
3 mercial for commercial distribution before the estab-  
4 lishment of the Interpretive Criteria Website, a hold-  
5 er of an approved application under section 505 or  
6 section 351 of the Public Health Service Act, as ap-  
7 plicable, for each such drug—

8                 “(A) not later than 1 year after establish-  
9 ment of the Interpretive Criteria Website, shall  
10 submit to the Secretary a supplemental applica-  
11 tion for purposes of changing the drug’s label-  
12 ing to substitute a reference or hyperlink to  
13 such Website for any susceptibility test inter-  
14 pretive criteria and related information; and

15                 “(B) may begin distribution of the drug in-  
16 volved upon receipt by the Secretary of the sup-  
17 plemental application for such change.

18                 “(2) DRUGS MARKETED SUBSEQUENT TO ES-  
19 TABLISHMENT OF INTERPRETIVE CRITERIA  
20 WEBSITE.—With respect to antimicrobial drugs law-  
21 fully introduced or delivered for introduction into  
22 interstate commerce for commercial distribution on  
23 or after the date of the establishment of the Inter-  
24 pretive Criteria Website, the labeling for such a drug  
25 shall include, in lieu of susceptibility test interpretive

1       criteria and related information, a reference to such  
2       Website.

3       “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-  
4       MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

5           “(1) IN GENERAL.—Notwithstanding sections  
6       501, 502, 510, 513, and 515, if the conditions speci-  
7       fied in paragraph (2) are met (in addition to other  
8       applicable provisions under this chapter) with re-  
9       spect to an antimicrobial susceptibility testing device  
10      described in subsection (f)(1), the Secretary may au-  
11      thorize the marketing of such device for a use de-  
12      scribed in such subsection.

13       “(2) CONDITIONS APPLICABLE TO ANTI-  
14      MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—  
15      The conditions specified in this paragraph are the  
16      following:

17           “(A) The device is used to make a deter-  
18       mination of susceptibility using susceptibility  
19       test interpretive criteria that are—

20           “(i) included in a standard recognized  
21       by the Secretary under subsection (c); or

22           “(ii) otherwise listed on the Interpre-  
23       tive Criteria Website under subsection  
24       (b)(2).

1                 “(B) The labeling of such device promi-  
2                 nently and conspicuously—

3                     “(i) includes a statement that—

4                         “(I) the device provides informa-  
5                 tion about the susceptibility of bac-  
6                 teria and fungi to certain drugs; and

7                         “(II) the safety and efficacy of  
8                 such drugs in treating clinical infec-  
9                 tions due to such bacteria or fungi  
10                 may not have been established in ade-  
11                 quate and well-controlled clinical trials  
12                 and the clinical significance of such  
13                 susceptibility information in those in-  
14                 stances is unknown;

15                 “(ii) includes a statement directing  
16                 health care practitioners to consult the ap-  
17                 proved labeling for drugs tested using such  
18                 a device, to determine the uses for which  
19                 the Food and Drug Administration has ap-  
20                 proved such drugs; and

21                 “(iii) includes any other statement the  
22                 Secretary determines appropriate to ade-  
23                 quately convey the limitations of the data  
24                 supporting the interpretive criteria de-  
25                 scribed in subparagraph (A).

1       “(f) DEFINITIONS.—In this section:

2           “(1) The term ‘antimicrobial susceptibility test-  
3           ing device’ means a device that utilizes susceptibility  
4           test interpretive criteria to determine and report the  
5           in vitro susceptibility of certain microorganisms to a  
6           drug (or drugs).

7           “(2) The term ‘qualified infectious disease  
8           product’ means a qualified infectious disease product  
9           designated under section 505E(d).

10          “(3) The term ‘susceptibility test interpretive  
11           criteria’ means—

12           “(A) one or more specific numerical values  
13           which characterize the susceptibility of bacteria  
14           or other microorganisms to the drug tested; and

15           “(B) related categorizations of such sus-  
16           ceptibility, including categorization of the drug  
17           as susceptible, intermediate, resistant, or such  
18           other term as the Secretary determines appro-  
19           priate.

20          “(4)(A) The term ‘antimicrobial drug’ means,  
21           subject to subparagraph (B), a systemic anti-  
22           bacterial or antifungal drug that—

23           “(i) is intended for human use in the treat-  
24           ment of a disease or condition caused by a bac-  
25           terium or fungus;

1               “(ii) may include a qualified infectious dis-  
2               ease product designated under section 505E(d);  
3               and

4               “(iii) is subject to section 503(b)(1).

5               “(B) If provided by the Secretary through regu-  
6               lations, such term may include—

7               “(i) drugs other than systemic anti-  
8               bacterial and antifungal drugs; and

9               “(ii) biological products (as such term is  
10               defined in section 351 of the Public Health  
11               Service Act) to the extent such products exhibit  
12               antimicrobial activity.

13               “(g) RULE OF CONSTRUCTION.—Nothing in this sec-  
14               tion shall be construed—

15               “(1) to alter the standards of evidence—

16               “(A) under subsection (c) or (d) of section  
17               505, including the substantial evidence stand-  
18               ard in section 505(d), or under section 351 of  
19               the Public Health Service Act (as applicable);  
20               or

21               “(B) with respect to marketing authoriza-  
22               tion for devices, under section 510, 513, or 515;

23               “(2) to apply with respect to any drug, device,  
24               or biological product, in any context other than—

25               “(A) an antimicrobial drug; or

1                 “(B) an antimicrobial susceptibility testing  
2                 device that uses susceptibility test interpretive  
3                 criteria to characterize and report the in vitro  
4                 susceptibility of certain bacteria, fungi, or other  
5                 microorganisms to antimicrobial drugs in ac-  
6                 cordance with this section; or

7                 “(3) unless specifically stated, to have any ef-  
8                 fect on authorities provided under other sections of  
9                 this Act, including any regulations issued under such  
10                 sections.”.

11                 (b) CONFORMING AMENDMENTS.—

12                 (1) REPEAL OF RELATED AUTHORITY.—Section  
13                 1111 of the Food and Drug Administration Amend-  
14                 ments Act of 2007 (42 U.S.C. 247d–5a; relating to  
15                 identification of clinically susceptible concentrations  
16                 of antimicrobials) is repealed.

17                 (2) MISBRANDING.—Section 502 of the Federal  
18                 Food, Drug, and Cosmetic Act (21 U.S.C. 352), as  
19                 amended by section 1, is further amended by adding  
20                 at the end the following:

21                 “(ee) If it is an antimicrobial drug and its labeling  
22                 fails to conform with the requirements under section  
23                 511(d).”.

24                 (3) RECOGNITION OF INTERPRETIVE CRITERIA  
25                 AS DEVICE STANDARD.—Section 514(c)(1)(A) of the

1       Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2       360d(c)(1)(A)) is amended by inserting after “the  
3       Secretary shall, by publication in the Federal Reg-  
4       ister” the following: “(or, with respect to suscepti-  
5       bility test interpretive criteria or standards recog-  
6       nized or otherwise listed under section 511, by post-  
7       ing on the Interpretive Criteria Website in accord-  
8       ance with such section)”).

9           (c) REPORT TO CONGRESS.—Not later than two  
10 years after the date of enactment of this Act, the Sec-  
11 retary of Health and Human Services shall submit to the  
12 Committee on Energy and Commerce of the House of  
13 Representatives and the Committee on Health, Education,  
14 Labor, and Pensions of the Senate a report on the  
15 progress made in implementing section 511 of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as  
17 amended by this section.

18           (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-  
19 TERIA WEBSITE.—Chapter 35 of title 44, United States  
20 Code, shall not apply to the collection of information from  
21 interested parties regarding the updating of lists under  
22 paragraph (2) of subsection (b) of section 511 of the Fed-  
23 eral Food, Drug, and Cosmetic Act (as amended by sub-  
24 section (a)) and posted on the Interpretive Criteria

1 Website established under paragraph (1) of such sub-  
2 section (b).

3 (e) NO EFFECT ON HEALTH CARE PRACTICE.—  
4 Nothing in this Act (including the amendments made by  
5 this Act) shall be construed to restrict, in any manner,  
6 the prescribing or administering of antibiotics or other  
7 products by health care practitioners, or to limit the prac-  
8 tice of health care.

